2009 CON Seminar







- MRI
- PET
- Lithotripsy (UESWL)
- BMT
- Heart/Lung & Liver
- Pancreas

CON Review Standards for MRI Services

- •Section 1 Applicability
- •Section 2 Definitions (Addition of MRI Simulator)
- •Section 3 Initiation
- ✓ Fixed 6000 AAPs
- ✓ Mobile 5500 AAPs
 - ❖ Urban Host 600 AAPs (within 20-mile radius)
 - Rural Host 400 AAPs (within 75-mile radius)
- **✓** Conversion
 - ❖6000 APs (locate at host site or w/i relocation zone)
 - ❖4000 APs (locate at host site or w/i relocation zone)
 - ❖ 3000 APs (locate at host site only)
- •Section 4 Replacement
 - ✓ Fixed 6000 APs
 - ✓ Mobile 5500 APs
 - ✓ Pediatric 3500 APs

CON Review Standards for MRI Services

- Section 5 Expansion
 - ✓ Fixed 1100APs
 - ✓ Mobile 9000 APs
 - ✓ Pediatric 3500 APs
- Section 6 Relocation (Fixed Units Only)
 - ✓ Service
 - **❖** 6000 APs/unit
 - ❖ Within relocation zone 10 miles (urban and rural)
 - Operational 36-months
 - ✓ A la carte
 - **❖** 6000 APs/unit
 - ❖ Within relocation zone 10 miles (urban and rural)
 - Operational 36-months

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CON Review Standards for MRI Services

- Section 7 Acquisition
 - ✓ Service (Volume waived for 1st acquisition after July 1, 1997)
 - ✓ 2nd Acquisition
 - **❖** Fixed − 6000 APs
 - ❖ Mobile 5500 APs
 - ❖ Pediatric 3500 APs
 - ✓ Al a carte
 - No volume requirements
 - Must meet subsection 7(2) requirements or sections 3 or 4
- Section 8 Research Units
- Section 9 Dedicated Pediatric Unit
- Section 10 IMRI
 - ✓ Pilot project ends 12/31/2010

CON Review Standards for MRI Services

- Section 11 Medicaid
 - ✓ Fixed documentation for applicant
 - ✓ Mobile documentation for each mobile host site
- Section 12 Project Delivery Requirements
 - ✓ Subsection 4 12 month waiting period for conversion to fixed
 - ✓ Subsection 1(d)(i) minimum average annual utilization
 - ✓ Subsection 1(e)(i) & (ii) notification of date of operation, addition, deletions or changes in host sites
- Section 13 MRI Procedures Adjustments
- Section 14 Documentation of Actual Utilization
 - ✓ MRI List in effect on date application is deemed submitted

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CON Review Standards for MRI Services

- Section 15 Methodology for Computing AAPs
- Section 16 Commitment of AAPs
 - ✓ Use of AAPs from entire mobile route
 - ✓ Signed & dated data commitments submitted with application (forms 220 & 220-A)
 - ✓ 100% commitment from a service
 - ✓ No withdrawals during 120-day review cycle or after approval
 - ✓ Data is committed for 36 months
- Section 17 MRI Lists (May 1 and November 1)
 - ✓ MRI Service Utilization List and Available MRI Adjusted Procedures List
- Section 18 Prior CON Review Standards; Comparative Reviews
 ✓ Not subject to comparative review
- Section 19 Health Service Areas (HSA)

- Section 1 Applicability
- Section 2 Definitions
- Section 3 Requirements for Approval Fixed or Mobile
- Section 4 Initiation
 - ✓ Fixed 2600 PET Data Units
 - ✓ Mobile 2100 PET Data Units
 - ❖ Urban 360 PET Data Units within the planning area and 20-mile radius
 - ❖Rural 240 PET Date Units within the planning area
 - No volume requirement to initiate host site on existing route
 - ✓ Conversion of Mobile to Fixed
 - ❖ Urban Host 4500 PEs
 - ❖Rural Host 4000 PEs
 - ❖Can not become host site for 12 months after operation of fixed PET

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CON Review Standards for PET Scanner Services

- Section 5 Expansion
 - ✓ Urban Fixed 5500 PEs
 - ✓ Rural Fixed 5000 PEs
 - ✓ Urban Mobile 5000 PEs (at least one urban host)
 - ✓ Rural Mobile 4500 PEs (only rural hosts)
 - ✓ Expand Fixed Service to Initiate Mobile Route
 - ❖ Urban Fixed 5500 PEs
 - ❖Rural Fixed 5000 PEs
- Section 6 Replacement
 - ✓ Fixed 4500 PEs
 - ✓ Mobile 3000 PEs
 - ✓ Volume exemption for replacing PET with PET/CT

(Operational before 1-1-05 and not a PET/CT)

- Section 7 Acquisition of an Existing PET Scanner Unit
 ✓ A la carte no volume requirements
- Section 8 Acquisition of an Existing PET Scanner Service
 ✓ No volume requirements
- Section 9 Relocation (Fixed Service Only)
 - ✓ Service
 - Operational 36 months
 - ❖ New site within relocation zone (urban − 10 miles, rural − 25 miles)
 - ✓ A la carte
 - ❖ Operational 36 months
 - New site within relocation zone (urban 10 miles, rural 25 miles)
- Section 10 Dedicated Research PET Scanner

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CON Review Standards for PET Scanner Services

- Section 11 Dedicated Pediatric PET Scanner
- Section 12 Additional Requirements for Mobile
- Section 13 Medicaid
 - ✓ Fixed documentation for applicant
 - ✓ Mobile documentation for each mobile host site
- Section 14 Project Delivery Requirements All
 - ✓ Subsection 1(v)(iii) minimum average annual utilization (1500 PEs per unit after second 12 months for mobile and fixed)
- Section 15 Project Delivery Requirements Mobile
- Section 16 Determination of PET Equivalents
 - ✓ Worksheet form 732
- Section 17 Methodology for Computing PET Data Units
 - ✓ New cancer cases, diagnostic cardiac cath sessions & intractable epilepsy

- Section 18 Commitment of New Cancer Cases
 - ✓ Gov. body resolution
 - ✓ 5-year data commitment for new cancer cases
 - ✓ Fixed Commitments from Planning Area (PA)
 - ✓ Mobile Commitments from PA of host site or w/i 75 miles of host in rural county/25 miles urban county
 - ✓ Cannot be a current service provider or have approval (fixed or mobile)
 - ✓ Not previously committed data or 5 years elapsed
 - ✓ Withdrawal of data after CON denial, CON-withdrawn or expired (Gov. body resolution)
- Section 19 Documentation of New Cancer Cases
 - ✓ Letter from State Registrar
 - ✓ Most recent cancer registry pursuant to advisory on CON web site

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CON Review Standards for PET Scanner Services

- Section 20 Commitment of Diagnostic Card Cath (DCC)
 - ✓ Gov. body resolution
 - ✓ 5-year data commitment for new cancer cases
 - ✓ Fixed Commitments from Planning Area (PA)
 - ✓ Mobile Commitments from PA of host site or w/i 75 miles of host in rural county/25 miles urban county
 - ✓ Cannot be a current service provider or have approval (fixed or mobile)
 - ✓ Not previously committed data or 5 years elapsed
 - ✓ DCC cases from most recent annual hospital survey
 - ✓ Withdrawal of data after CON denial, CON-withdrawn or expired (Gov. body resolution)

- Section 21 Commitment of Intractable Epilepsy (IE) Cases
 - ✓ Gov. body resolution
 - ✓ 5-year data commitment for new cancer cases
 - ✓ Fixed Commitments from Planning Area (PA)
 - ✓ Mobile Commitments from PA of host site or w/i 75 miles of host in rural county/25 miles urban county
 - ✓ Cannot be a current service provider or have approval (fixed or mobile)
 - ✓ Not previously committed data or 5 years elapsed
 - ✓ IE cases from most recent MIDB data
 - ✓ Withdrawal of data after CON denial, CON-withdrawn or expired (Gov. body resolution)

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CON Review Standards for PET Scanner Services

- Section 22 Health Service Areas (HSA)
- Section 23 Planning Areas
- Section 24 Department Inventory
- Section 25 Comparative Reviews/Prior Planning Policies
 - ✓ Not subject to comparative review

CON Review Standards for UESWL Services

- Section 1 Applicability
- Section 2 Definitions
- Section 3 Initiation
 - ✓ Project 1000 procedures per methodology in Section 13
 - ✓ MIDB data
 - ✓ Proposed site offers all seven services cited under this section
- Section 4 Replacement
 - ✓ 1000 procedures per unit (fixed or mobile)
 - \checkmark Exception to 4(1) replace existing fixed unit with a mobile
 - ✓ Upgrade \$125,000 or less over consecutive 24-month period
- Section 5 Additional Requirements Mobile
 - ✓ Add Michigan host site to non-state route
 - \checkmark 100 procedures to add host site if the region is not served by that route

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CON Review Standards for UESWL Services

- Section 6 Acquisition (Fixed or Mobile)
 - ✓ Service
 - ❖ First acquisition after May 2, 1998 no volume requirements
 - ❖ Second acquisition − 1000 procedures per unit
 - ✓ A la carte
 - ❖ 1000 procedures per unit
- Section 7 Relocation (Fixed Only)
 - ✓ Service
 - Operational for 36 months
 - New site is within relocation zone (25-mile radius)
 - ❖ 1000 procedures per unit
 - ✓ A la carte
 - ❖ Operational for 36 months
 - New site is within relocation zone (25-mile radius)
 - ❖ 1000 procedures per unit

CON Review Standards for UESWL Services

- Section 8 Expansion (Fixed or Mobile)
 - ✓ 1800 procedures per unit, existing and approved
 - ✓ 1000 projected procedures per unit, existing and proposed
- Section 9 Medicaid
 - ✓ Fixed documentation for applicant
 - ✓ Mobile documentation for each mobile host site
- Section 10 Project Delivery Requirements All
- Section 11 Project Delivery Requirements Mobile
 - ✓ Notification to Department 30 days prior to deleting host site
- Section 12 Health Service Area (HSA)
- Section 13 Methodology for Projecting UESWL Procedures
 - ✓ MIDB Data
 - ✓ Appendix A Factors

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CON Review Standards for UESWL Services

- Section 14 Requirements for MIDB Data Commitments
 - ✓ 5-year commitment
 - ✓ 100% of data for the facility
 - ✓ If current service provider, can't commit data to another service
 - ✓ Fixed site within same Region as proposed service
 - ✓ Mobile host at least one proposed host site within same region
- Section 15 Comparative Reviews/Prior Planning Policies
 - ✓ Not subject to comparative review

CON Review Standards for BMT Services

- Section 1 Applicability
- Section 2 Definitions
- Section 3 Initiate Bone Marrow Transplantation Service
 - ✓ Requires specialty services
 - ✓ Limited to 3 adult BMT services in the planning area (State)
 - ✓ Limited to 3 pediatric BMT services (2 in planning area 1 and 1 in planning area 2, as defined)
- Section 4 Requirements for Comparative Reviews
- Section 5 Medicaid
 - ✓ Documentation for applicant
- Section 6 Project Delivery Requirements

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CON Review Standards for BMT Services

- Section 7 Documentation of Projections
- Section 8 Acquisition of a BMT Service by Cancer Hospital
- Section 9 Health Service Areas (HSA)
- Section 10 Department Inventory of BMT Services
- Section 11 Comparative Reviews/Prior Planning Policies
 - ✓ Subject to comparative review

CON Review Standards for Heart/Lung & Liver Transplantation Services

- Section 1 Applicability
- Section 2 Definitions
- Section 3 Initiation
 - ✓ Requires specialty services
 - ✓ Medicaid
 - ❖ Documentation for applicant
- Section 4 Additional Requirements for Heart/Lung
 - ✓ Limited to 3 services in the planning area (State)
 - ✓ Projected 12 transplants per year by 2nd year of operation
 - ✓ Renal transplant program required (onsite or offsite-w/i hospital subarea)
 - ✓ Exemption for joint sharing

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CON Review Standards for Heart/Lung & Liver Transplantation Services

- Section 5 Additional Requirements for Liver
 - ✓ Limited to 3 services in the planning area (State)
 - ✓ Projected 12 transplants per year by 2nd year of operation
 - ✓ Renal transplant program required (onsite or offsite-w/i hospital subarea)
 - ✓ Specialty services required
- Section 6 Requirements for Comparative Reviews
- Section 7 Project Delivery Requirements
- Section 8 Additional Requirements All
 - ✓ Written agreement w/Federally approved organ procurement organization
 - ✓ Other specialty services required
- Section 9 Additional Requirements Heart, Heart/Lung, Lung
 - ✓ Special staffing requirements

CON Review Standards for Heart/Lung & Liver Transplantation Services

- Section 10 Additional Requirements Liver
 ✓ Special staffing requirements
- Section 11 Documentation of Projections
- Section 12 Health Service Areas (HSA)
- Section 13 Comparative Reviews/Prior Planning Policies

✓ Subject to comparative review

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CON Review Standards for Pancreas Transplantation Services

- Section 1 Applicability
- Section 2 Definitions
- Section 3 Requirements for Approval All Applicants
 - ✓ Requires specialty services
 - ✓ Projected 2 transplants per year by 2^{nd} year of operation
 - ✓ Medicaid
 - ❖ Documentation for applicant
- Section 4 Project Delivery Requirements
 - ✓ Requires 80 on-site transplants over last 24 months and biennially thereafter (at least 4 pancreas and balance renal transplants)
- Section 5 Documentation of Projections
- Section 6 Comparative Reviews/Prior Planning Policies
 - ✓ Not subject to comparative review